SPECIAL
510(K) SUMMARY

APR 11 2013

Submitter Information:

Submitter's Name:	Incite Innovation LLC
Address:	P.O. Box 15388 1500 Main Street, Ste 2410 Springfield, MA 01115-5707
Telephone:	413-382-0212
Contact Person:	John Kirwan

Date Prepared:	February 6, 2013
Device Trade Name:	Incite Anchored Cervical Interbody Fusion (ACI) Device
Common/Usual Name:	Spinal Intervertebral body fixation orthosis
Classification:	21 CFR §888.3080
Class:	II
Product Code:	OVE
Predicate Device:	Incite Anchored Cervical Interbody Device K122008

Intended Use:

The Incite Anchored Cervical Interbody Device is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Incite Anchored Cervical Interbody Device is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental fixation, i.e. an anterior cervical plate, is required to properly utilize this system.

Device Description:

The Incite Anchored Cervical Interbody Fusion Device acts as a spacer to maintain proper Intervertebral and vertebral body spacing and angulation. The Incite Anchored Cervical Interbody Fusion Device is manufactured from PEEK and Ti6Al4V titanium alloy with tantalum radiopaque markers

Comparison to Predicate Device(s):
The indication for use and material composition of the 16mm wide x14mm deep Incite Anchored Cervical Interbody Fusion (ACI) Device are the same as the currently cleared predicate device, Incite Anchored Cervical Interbody Fusion (ACI) Device. The only difference is the addition of a larger footprint implant, 16x14mm:

Incite Anchored Cervical Interbody Fusion (ACI) Device (K122008) (W x D)	Incite Anchored Cervical Interbody Fusion (ACI) Device (W x D)
EXISTING SIZES: 14x14mm, 14x12mm	NEW SIZE: 16 x14mm

The dimensional differences between the subject device and the predicate are not considered significant because the new size does not introduce a new worst case condition (e.g. introduction of a new region with decreased cross sectional area compared to the predicate) and therefore does not raise new questions regarding safety and effectiveness of the device.

Performance Standards:
In consideration of design control activities including risk analysis the non-clinical performance testing performed on the predicate device, Incite Anchored Cervical Interbody Fusion (ACI) Device (K122008), including static compression, static torsion, subsidence, and expulsion are applicable in the characterization of the new size because the new size does not introduce a new worst case condition (e.g. introduction of a new region with decreased cross sectional area compared to the predicate), therefore additional mechanical testing on the new size is not warranted.

Performance and SE Determination:
Based on the supporting documentation within this premarket notification, the subject device demonstrates substantial equivalence to the listed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2013

Incite Innovations, LLC
% Mr. John Kirwan
President
P.O. Box 15388
1500 Main Street, Suite 2410
Springfield, Massachusetts 01115

Re: K130306
Trade/Device Name: Incite Anchored Cervical Interbody Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: March 14, 2013
Received: March 15, 2013

Dear Mr. Kirwan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130306

The Incite Anchored Cervical Interbody Device is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Incite Anchored Cervical Interbody Device is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental fixation, i.e. an anterior cervical plate, is required to properly utilize this system.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices